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Thoracic and Cardiovascular Surgery

EXPERT REPORT

Tackett v. Providence Sacred Heart

I, Alexander R. Marmureanu, M.D. declare as follows:

I currently practice Thoracic and Cardiovascular Surgery in Los Angeles, CA. I am Board Certified in Cardiothoracic Surgery and General Surgery and licensed to practice in the states of California and New York. I am also an Assistant Professor of Surgery and Vice Chair of the Bylaws Committee at the School of Medicine at California University of Science and Medicine.

I am currently the Chief of Staff at Hollywood Presbyterian Medical Center as well as the President and CEO of California Heart and Lung Surgery Medical Center in Los Angeles.

I am also the Director of Cardiothoracic Surgery at Centinela Hospital Medical Center and the Director of Cardiovascular Surgery at Southern California Hospital at Culver City.

My offices are located in Westwood, at 10921 Wilshire Blvd., #1205 Los Angeles, CA 90024, and at Centinela Hospital Medical Center on 501 East Hardy St. #315, Inglewood CA 90301.

I completed my General Surgery residency and a research fellowship at New York University Medical Center and Mt. Sinai Medical Center from 1994 – 2000. I then completed my Cardiothoracic Surgery fellowship at UCLA Medical Center from 2000 – 2002, where I served on the Faculty, before founding California Heart and Lung Surgery Center.

Currently, in addition to my Thoracic and Cardiovascular surgical practice, I continue to train both medical students, residents, fellows, as well as other surgeons. I also continue to publish and lecture on various topics in the field of Thoracic and Cardiovascular Surgery.

Through my education, training and professional experience, I am very familiar with Mrs. Tackett's medical conditions, treatment, and associated prognosis.

My opinions are based upon my medical education, thoracic and cardiovascular surgical training, practice, and experience, as well as the medical records, and all other documents that I have reviewed.

I reserve the right to supplement my opinion based upon the receipt of additional information.

My education and background are listed on the attached curriculum vitae, which sets forth my education, training, experience, and qualifications as a physician and expert.

DOCUMENTS REVIEWED

- Rocky Mountain Heart & Lung Medical Records
- Providence Sacred Heart Medical Records
- Cabinet Peaks Medical Records
- Pharm Records
- Death Certificate
- State Case Complaint
- Matt West's Report
- Nicole Desiree Haats FNP Deposition
- William Highfill MD Deposition

LITERATURE REVIEWED

- Stevenson, Lynne Warner, and Akshay S Desai. “Selecting patients for discussion of the ICD as primary prevention for sudden death in heart failure.” *Journal of cardiac failure* vol. 12,6 (2006): 407-12.
- Cleland, John G F et al. “The effect of cardiac resynchronization on morbidity and mortality in heart failure.” *The New England journal of medicine* vol. 352,15 (2005): 1539-49.
- Bristow, Michael R et al. “Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure.” *The New England journal of medicine* vol. 350,21 (2004): 2140-50.
- Bradley, David J et al. “Cardiac resynchronization and death from progressive heart failure: a meta-analysis of randomized controlled trials.” *JAMA* vol. 289,6 (2003): 730-40.
- Gasparini, Maurizio et al. “Comparison of 1-year effects of left ventricular and biventricular pacing in patients with heart failure who have ventricular arrhythmias and left bundle-branch block: the Bi vs Left Ventricular Pacing: an International Pilot Evaluation on Heart Failure Patients with Ventricular Arrhythmias (BELIEVE) multicenter prospective randomized pilot study.” *American heart journal* vol. 152,1 (2006): 155.e1-7.
- Lane, Rebecca E et al. “Prediction and prevention of sudden cardiac death in heart failure.” *Heart (British Cardiac Society)* vol. 91,5 (2005): 674-80.

Informed Consent, Patient Centered Care and Shared Decision-Making

- Weinstein JN, Clay K, Morgan TS. Informed patient choice: patient-centered valuing of surgical risks and benefits. *Health Aff (Millwood)*. 2007;26(3):726-730.
- Bernat JL, Peterson LM. Patient-centered informed consent in surgical practice. *Arch Surg*. 2006;141(1):86-92.
- American Medical Association. (2020). Informed Consent. Code of Medical Ethics Opinion 2.1. 1. American Medical Association.

American College of Cardiology/American Heart Association Guidelines

- The ACC/AHA guidelines are explicit in their recommendation of implantable cardioverter-defibrillator therapy for the primary prevention of sudden cardiac death in patients with:
 - Left ventricular ejection fraction (LVEF) $\leq 30\text{--}35\%$ and New York Heart Association functional class II or III symptoms, while undergoing optimized medical therapy.
 - This is a Class I recommendation supported by Level A evidence for ischemic cardiomyopathy and Level B evidence for nonischemic cardiomyopathy.
- Implantable cardioverter-defibrillator (ICD) therapy is strongly recommended for patients like Mrs. Robbie Tackett, who had a documented EF of 20%, placing her at a significantly elevated risk for life-threatening ventricular arrhythmias and sudden cardiac death.

ICD & CRT Benefits in High-Risk Heart Failure Patients

- ICD Benefits:
 - ICDs are highly effective at preventing sudden cardiac death by detecting and terminating life-threatening ventricular arrhythmias (ventricular tachycardia or fibrillation).
 - Studies have demonstrated a 20–60% reduction in total mortality in patients with severe left ventricular dysfunction treated with ICDs over a follow-up of 2–5 years.
 - ICDs have shown to reduce all-cause mortality by:
 - 31% over two years in patients with low EF and previous myocardial infarction.
 - 23% over five years in patients with low EF, NYHA class II/III, and either ischemic or nonischemic cardiomyopathy.
- Cardiac Resynchronization Therapy (CRT) Benefits:
 - Cardiac resynchronization therapy improves the synchrony of ventricular contractions, reducing heart failure symptoms and improving quality of life in patients with reduced EF and prolonged QRS interval (e.g., left bundle branch block, as documented in Mrs. Tackett's case).
 - CRT has been shown to:
 - Substantially reduce complications & mortality from progressive heart failure.
 - Improve exercise capacity, functional class, and overall quality of life.
 - Lead to favorable left ventricular remodeling by decreasing dyssynchrony and mitral regurgitation, resulting in improved cardiac function and reduced heart failure symptoms.
 - The combination of CRT and ICD has been shown to significantly reduce mortality from all causes in patients with advanced heart failure and prolonged QRS intervals.

ICD & CRT in Preventing Sudden Cardiac Death

- Prevention of Sudden Cardiac Death (SCD):
 - Sudden cardiac death remains a devastating complication of heart failure, responsible for 300,000–400,000 deaths annually in the United States.
 - Ventricular arrhythmias, including monomorphic ventricular tachycardia and ventricular fibrillation, account for the majority of SCD events.
 - Patients with an LVEF <35% are at significant risk for SCD despite optimized medical therapy. Without an ICD, these patients face drastically elevated mortality rates.
- Clinical Trials Supporting ICD Efficacy:
 - Clinical trials have confirmed that ICDs are highly effective at preventing SCD and reducing all-cause mortality. Evidence includes:
 - ICDs reduce mortality by 20–60% compared to antiarrhythmic drug therapy in patients with poor left ventricular function and documented arrhythmias.
 - For primary prevention in patients with no arrhythmia but severely reduced EF, ICDs lower mortality rates by up to 31% over two years and 23% over 5 years.
- Cost-Effectiveness and Patient Outcomes:
 - ICDs and CRT devices have been shown to be cost-effective interventions in high-risk populations, offering substantial mortality benefits and peace of mind to patients with life-threatening ventricular arrhythmias.
- CRT, particularly when combined with ICD, has been shown to:
 - Reduce heart failure-related hospitalizations.
 - Address the mechanical inefficiencies caused by dyssynchrony in patients with LBBB and other conduction abnormalities.
 - Improve survival rates by reducing mortality from progressive heart failure and sudden cardiac death.

Guidelines as Applicable to Mrs. Tackett

- Mrs. Tackett presented with multiple clinical indicators that strongly qualified her for ICD and CRT therapy under the ACC/AHA guidelines:
 - Severely reduced LVEF of 20%: This placed her well below the 35% threshold for ICD and CRT candidacy.
 - NYHA Class II/III Symptoms: Documented symptoms of heart failure confirmed her eligibility for primary prevention with ICD therapy.

- Left Bundle Branch Block: This is a key indicator for CRT in patients with dyssynchronous heart failure, as it correlates with inefficient ventricular contractions and worse outcomes.
- Nonischemic Cardiomyopathy: ICD therapy is supported by Level B evidence for this population, which is applicable to Mrs. Tackett's condition.
- Despite her critical risk profile, no documented steps were taken to:
 - Refer her to an electrophysiologist for ICD evaluation.
 - Consider CRT to address her dyssynchrony and improve her cardiac function.
 - Discuss treatment options with Mrs. Tackett and involve her in shared decision-making regarding potentially life-saving therapies in accordance with the guidelines below.

INFORMED CONSENT, PATIENT CENTERED CARE & SHARED DECISION-MAKING

In contemporary medical practice, informed consent, patient-centered care, and shared decision-making form the cornerstone of ethical and legal standards for physician-patient relationships. These principles emphasize respect for patient autonomy, active patient participation, and collaborative treatment planning.

In the case of Mrs. Robbie Tackett, these standards were not upheld, as her care at Providence Sacred Heart Medical Center demonstrated significant failures in communication, shared decision-making, and informed consent. By failing to provide clear communication and a comprehensive exchange of information, the medical team disregarded Mrs. Tackett's values, preferences, and personal goals, which should have been at the heart of clinical decision-making.

Physicians are entrusted with the responsibility to provide accurate, complete, and sensitive information tailored to each patient's preferences. This obligation reflects the ethical principle of autonomy and ensures that individuals can make informed choices regarding their health. In Mrs. Tackett's case, the following components of informed consent were critically absent:

- Failure to Clearly Communicate the Diagnosis: Mrs. Tackett had severe nonischemic cardiomyopathy, an ejection fraction of 20%, and left bundle branch block, placing her at high risk for sudden cardiac death. However, there is no documentation showing that her physicians clearly communicated the severity of her condition or her risk of SCD. This lack of transparency undermined trust and prevented her from understanding the need for urgent intervention.
- Failure to Explain the Nature and Purpose of Recommended Interventions: Implantable cardioverter defibrillator placement and cardiac resynchronization therapy are standard treatments for patients with Mrs. Tackett's risk profile, as outlined by ACC/AHA guidelines. However, the medical records do not reflect any discussion with Mrs. Tackett about these

potentially life-saving treatments, how they work, or their intended outcomes. This omission deprived her of critical knowledge that could have informed her decisions.

- **Failure to Discuss the Burdens, Risks, and Expected Benefits of All Available Options:** There is no evidence that Mrs. Tackett was informed of the risks and benefits associated with ICD and CRT therapy, alternative treatments, or the consequences of forgoing these interventions. Without this information, she was unable to fully weigh her options and make an informed decision about her care.

Informed consent is not simply evidenced by a patient's signature on a form—it is an ongoing dialogue that evolves as treatment plans develop. This communication should have continued throughout Mrs. Tackett's care, from the initial discussions about her diagnosis to the consideration of ICD and CRT therapy. The failure to engage her in these critical conversations represents a fundamental breach of the principles of informed consent.

In the modern era, patient-centered care has shifted the clinical paradigm from a paternalistic model to one that prioritizes collaboration. Within this framework, shared decision-making is a key element. In Mrs. Tackett's case, however, this collaborative approach was entirely absent. Key failings included:

- **Lack of Balanced, Evidence-Based Information on All Options:** Mrs. Tackett was not provided with evidence-based information about her condition or the available treatment options, such as ICD and CRT therapy. Without this foundational knowledge, she was unable to meaningfully participate in decisions about her care.
- **Failure to Use Clear and Understandable Language:** Communication techniques like “teach-back” could have been used to confirm that Mrs. Tackett understood the complexities of her condition and the proposed treatments. Instead, the lack of documented discussions suggests a failure to ensure that information was presented in an accessible and meaningful way.
- **Disregard for Mrs. Tackett's Values and Preferences:** Patient-centered care requires physicians to understand and respect each patient's unique values and preferred role in decision-making. There is no indication that Mrs. Tackett's personal goals, concerns, or preferences were elicited or considered in her treatment planning.
- **Failure to Arrive at a Collaborative Treatment Decision:** A shared decision-making process would have allowed Mrs. Tackett and her physicians to reach a consensus that balanced clinical realities with her personal wishes. The absence of this process denied her the opportunity to take an active role in her care and undermined the trust essential to the physician-patient relationship.

Informed consent and shared decision-making are guided by ethical principles and reinforced by legal requirements. In Mrs. Tackett's case, the following principles were violated:

- **Autonomy:** Mrs. Tackett was not given the information necessary to make an informed, autonomous decision regarding her care.
- **Beneficence and Nonmaleficence:** By failing to recommend and implement ICD and CRT therapy, the medical team neglected to act in her best interests and failed to minimize her risk of harm.

- Justice: The systemic failures at Providence Sacred Heart Medical Center reflect broader inequities in ensuring equitable access to appropriate care for high-risk cardiac patients.

Legally, these failures represent a breach of the standard of care expected of a reasonably prudent healthcare provider operating under similar circumstances within the state of Washington. Institutional policies and accreditation standards, such as those set by The Joint Commission, require that informed consent be obtained and documented to protect patients' rights and mitigate physician liability. However, in Mrs. Tackett's case, these requirements were not met.

Mrs. Tackett's case highlights the importance of moving beyond passive informed consent toward a truly collaborative model of care. This would have involved:

- Engaging Mrs. Tackett at the outset of her care planning would have allowed her to voice her preferences and concerns, ensuring that her values were central to clinical decision-making.
- Tools such as risk calculators and outcome tables could have helped Mrs. Tackett contextualize the potential benefits and harms of ICD & CRT therapy.
- Encouraging Mrs. Tackett to ask questions and express her concerns would have fostered trust and improved satisfaction with her care.

By failing to implement these strategies, the medical team missed critical opportunities to involve Mrs. Tackett in her care and prevent her tragic, preventable death.

In Mrs. Tackett's case, the principles of informed consent, patient-centered care, and shared decision-making were not upheld. The failure of Providence Sacred Heart Medical Center and its staff to engage her in these essential processes represents a significant deviation from the expected standard of care. These omissions directly contributed to Mrs. Tackett's preventable death, as she was denied the opportunity to make informed decisions about her treatment and receive life-saving interventions.

FACTS

- Mrs. Robbie Tackett was a 51-year-old woman with a history of severe nonischemic cardiomyopathy, mitral regurgitation, left bundle branch block, and hypertension.
- She had been diagnosed with an ejection fraction of 20% and was identified as having chronic heart failure 6 months prior to her hospitalization in November 2018.
- On November 1, 2018, Mrs. Tackett was admitted to Providence Sacred Heart Medical Center for evaluation of stroke and heart failure.
- EKG findings included left ventricular hypertrophy, nonspecific intraventricular conduction delay, and inverted T-waves in inferior leads.
- Echocardiogram confirmed an EF of 20% with left ventricular dysfunction, severe cardiomyopathy, and no visible thrombus.
- Chest X-ray showed cardiomegaly, interstitial pulmonary edema & bilateral pleural effusions.

- Laboratory findings revealed significantly elevated troponin levels (2.3 ng/mL), consistent with cardiac stress or ischemic insult.
- Despite being on optimal medical therapy (carvedilol, lisinopril, spironolactone, atorvastatin), there was no referral to an electrophysiologist for evaluation of her high risk of SCD.
- Lack of referral for ICD placement or CRT was a clear departure from the standard of care.
- No evidence exists in the medical records of shared decision-making or discussions about the risks of her condition and available treatments.
- On July 31, 2019, Mrs. Tackett died of sudden cardiac death, a preventable outcome had appropriate interventions been implemented.

METHODOLOGY OF OPINIONS

The opinions provided herein are based on my education, training, clinical practice, and expertise as a board-certified thoracic and cardiovascular surgeon, as well as a thorough review of the relevant medical literature. In forming these opinions, I have applied the same well-established methodologies routinely utilized within the medical community for diagnosing and treating conditions similar to those affecting Mrs. Tackett. This includes a comprehensive evaluation of Mrs. Tackett's medical records, the amended complaint, and widely accepted clinical guidelines. My approach is consistent with the standards I uphold in my daily practice, particularly in the diagnosis and treatment of advanced heart failure and related conditions.

All of my opinions are provided to a reasonable degree of medical certainty and are based on my background and a comprehensive review of the relevant medical records, applicable facts, and established medical guidelines. These opinions are rendered in accordance with the standard of care and are consistent with the professional judgment expected of a qualified medical/surgical expert under similar circumstances. Should new evidence or additional medical records become available, I reserve the right to amend, supplement, or modify my opinions accordingly.

OPINIONS

- Sudden cardiac death is a predictable and preventable event in high-risk patients with severe left ventricular dysfunction and heart failure.
- The failure to offer ICD therapy or CRT to Mrs. Tackett represents a gross deviation from the standard of care as established by the ACC/AHA guidelines.
- With the appropriate interventions, including ICD and CRT, Mrs. Tackett's risk of sudden cardiac death would have been substantially reduced, and it is more likely than not that her life could have been saved.
- Mrs. Tackett exhibited multiple risk factors for SCD, including an EF of 20%, severe nonischemic cardiomyopathy, and LBBB. These findings should have prompted urgent consideration of ICD placement and CRT.
- Dr. Kavitha Chaganur and Dr. Timothy Ball failed to recognize and address her risk, violating the standard of care.

- The standard of care would have required:
 - Referral to an electrophysiologist for evaluation of ICD therapy due to an $EF \leq 35\%$.
 - Consideration of CRT in patients with LBBB and dyssynchrony.
- These steps were not taken, nor were they discussed with the patient in accordance with the informed consent and shared decision making practices.
- If an ICD and CRT had been provided, Mrs. Tackett's risk of sudden cardiac death would have been significantly reduced and more likely than not, she would still be alive today.
- The lack of documentation regarding shared decision-making or a referral represents a systemic failure to provide appropriate care.
- Providence Sacred Heart failed to ensure processes were in place to identify high-risk cardiac patients and escalate their care to an appropriate level.
- This institutional failure deprived Mrs. Tackett of the chance to receive life-saving interventions.
- Despite her persistent low EF, no process or policy ensured a referral to an electrophysiologist, CRT, or ICD placement.
- There is no documentation that Mrs. Tackett was informed of her risk for SCD or presented with treatment options such as BiV pacing, CRT, or ICD placement.
- This omission violated the principles of patient-centered care and informed consent.
- Mrs. Tackett's death more likely than not from ventricular arrhythmia was directly caused by the failure to implement ICD therapy, as per guidelines. Her death was preventable.

CONCLUSION

In my expert medical opinion:

- More likely than not, Mrs. Robbie Tackett died from a cardiac arrhythmia related to her untreated heart failure associated with a severely reduced ejection fraction.
- Failure to adhere to ACC/AHA guidelines for ICD placement and CRT therapy represented a gross departure from the standard of care, resulting in her preventable death on July 31, 2019.
- Providence Sacred Heart and its staff, including Dr. Chaganur and Dr. Ball, failed to exercise the degree of care, skill and learning expected of a reasonably prudent Cardiologist in the State of Washington acting in the same or similar circumstances in the care of Mrs. Tackett by failing to diagnose and address her high risk of sudden cardiac death. This failure, compounded by institutional deficiencies, directly contributed to her passing.
- In my opinion, the level of care, skill and learning applied to the care applied to Mrs. Tackett did not align with what could be reasonably expected of healthcare professionals in similar situations.
- Had Mrs. Tackett received an ICD and CRT as recommended by guidelines, more likely than not, she would be alive today.

In conclusion, it is my expert medical opinion that Mrs. Robbie Tackett's death was a preventable outcome caused by significant failures in medical management and systemic deficiencies. Providence Sacred Heart Medical Center and its medical personnel, including Dr. Kavitha Chaganur and Dr. Timothy Ball, did not meet the expected standard of care as defined by the professional norms of a reasonably prudent healthcare provider operating under similar circumstances within the state of Washington. This failure was rooted in their inability to properly diagnose and manage Mrs. Tackett's high risk of sudden cardiac death, a critical oversight that directly contributed to her tragic and preventable demise.

Specifically, the failure to refer Mrs. Tackett to an electrophysiologist for evaluation and implementation of ICD and CRT therapy, as recommended by ACC/AHA guidelines, constituted a gross deviation from the standard of care. Compounding this failure were systemic deficiencies at Providence Sacred Heart Medical Center, including the absence of protocols to identify high-risk cardiac patients and ensure the timely escalation of their care. Additionally, the lack of documentation regarding informed consent, shared decision-making, or the consideration of ICD and CRT therapies reflects a violation of patient-centered care principles and a disregard for Mrs. Tackett's substantial and well-documented risk of sudden cardiac death.

It is my opinion, within a reasonable degree of medical certainty, that had Mrs. Tackett received the recommended therapies, including ICD and CRT, her risk of sudden cardiac death would have been significantly reduced, and more likely than not, she would have been alive today.

I reserve the right to amend, supplement, or modify my opinions should new evidence or additional medical records become available.

A handwritten signature in black ink, appearing to read "Alex Marmureanu", written in a cursive style.

Alexander Marmureanu MD